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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,158	03/28/2001	Shouji Furusako	1110-0284P	5167

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EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,158	FURUSAKO ET AL.	
	Examiner	Art Unit	
	James L Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *29 and 30* is/are allowed.

6)☒ Claim(s) *15-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 19 August 2004 is acknowledged and has been entered. Claims 15-30 are newly added. Claims 1-14 have been cancelled. Claims 15-30 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15-26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 15-17, the interrelationships of the components of the method are not clear, e.g. it is not clear in who or what sepsis is being diagnosed, "the" C-terminus of "the" amino acid sequence is not clear absent a "SEQ ID NO:" identifier, and the relationship of measuring an amount to "the" measured value is not clear. The examiner would suggest: line 1, "diagnosing sepsis" --in a patient--; line 4, "body fluid" --sample from the patient--; line 7, "CD14 protein" --, SEQ ID NO: 1,--; line 8, "the measured" --amount--; line 8, "standard" --amount measured in body fluid samples--; and, line 9, "diagnose sepsis" --in the patient--.

Claim 16 is vague in the absence of recitation of deposit accession number to clearly identify the antibody/hybridoma because, absent the recitation of deposit accession number, it is not clear what structure and properties are encompassed by the named antibody. The examiner

would suggest: line 3, "antibody" --as produced by a hybridoma cell line deposited as FERM BP-7296--.

In claim 17, "mainly" is a relative term which renders the claim indefinite. The term is not defined by this claim, the specification does not provide a standard for ascertaining the requisite degree, and one in the art would not be reasonably apprised of the scope of the invention.

In claims 18-22, the interrelationships of the components of the method are not clear, e.g. recitations of "the" C-terminus of "the" amino acid sequence are not clear absent a "SEQ ID NO:" identifier. The claims should also conclude with a step relating the method result to the purpose of the method, preferably to the purpose as also set forth in the preamble of the claim.

In claims 19-20, recitations of "the reacted amount" lack antecedent basis and are not clear as to what is being measured.

Claim 21 is vague in the absence of recitation of deposit accession numbers to clearly identify the antibodies/hybridomas because, absent the recitation of deposit accession numbers, it is not clear what structure and properties are encompassed by the named antibodies. The examiner would suggest, for example: lines 2-3, "F1025-3-1 antibody" --as produced by a hybridoma cell line deposited as FERM BP-7296--; line 4, --the-- "F1025-3-1 antibody."

In claim 22, "mainly" is a relative term which renders the claim indefinite. The term is not defined by this claim, the specification does not provide a standard for ascertaining the requisite degree, and one in the art would not be reasonably apprised of the scope of the invention.

In claims 23-26, the interrelationships of the components of the method are not clear, e.g. recitations of "the" C-terminus of "the" amino acid sequence are not clear absent a "SEQ ID NO:" identifier; "the reacted amount" lacks antecedent basis and is not clear as to what is being measured. The claims should also conclude with a step relating the method result to the purpose of the method, preferably to the purpose as also set forth in the preamble of the claim.

In claims 25 and 26, "mainly" is a relative term which renders the claims indefinite. The term is not defined by these claims, the specification does not provide a standard for ascertaining the requisite degree, and one in the art would not be reasonably apprised of the scope of the invention.

Claims 23-28 are rejected under 35 U.S.C. § 102(b) as being anticipated by Stelter et al. (Eur. J. Biochem 236: 457, 1996) for reasons of record in the prior rejection of the similar subject matter of claims 5 and 13.

Stelter et al. teach determination of high molecular weight soluble CD14 (sCD14) in samples, including from human serum (see e.g. Table 2), with polyclonal anti-CD14 antibodies. The antibodies of the reference appear to anticipate the reagent antibodies as instantly claimed because antibodies to any immunogenic epitope of the full-length protein would be inherently found in the polyclonal antibody population and specifically bind thereto. Full-length sCD14 comprises the consecutive amino acid sequences as recited.

Claims 23-28 are rejected under 35 U.S.C. § 102(b) as being anticipated by Landmann et al. (J. Inf. Dis. 171: 639, 1995) for reasons of record in the prior rejection of the similar subject matter of claims 5 and 13.

Landmann et al. teach determination of high molecular weight soluble CD14 (sCD14) in samples, including from human serum (see e.g. page 642), with polyclonal anti-CD14 antibodies. The antibodies of the reference appear to anticipate the reagent antibodies as instantly claimed because antibodies to any immunogenic epitope of the full-length protein would be inherently found in the polyclonal antibody population and specifically bind thereto. Full-length sCD14 comprises the consecutive amino acid sequences as recited.

Claims 27-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Leturcq et al. (WO 94/28025) for reasons of record in the prior rejection of the similar subject matter of claims 5-8 and 11. Full-length sCD14 comprises the consecutive amino acid sequences as recited.

Applicant's arguments filed 19 August 2004 have been fully considered but they are not deemed to be persuasive. Applicant urges that the polyclonal antibodies, as a population, bind non-selectively to both low and high molecular weight forms in a sample. This is not found persuasive because the method claims are not limited to an isolated antibody population with the recited properties. Applicant's arguments are drawn to the population as a whole and are not found persuasive with regard to the inherent specific binding of antibody subpopulations in the polyclonal antibody population to their respective epitopes on the antigen. Moreover, applicant

urges that it is not predictable that amino acids in the 316-356 region form exposed epitopes. This is not found persuasive because the antibodies of the instant disclosure clearly bind to soluble CD14, i.e. the epitopes are exposed, and because it is notoriously old and well known in the art that C-terminal amino acid sequences are often exposed and elicit a high percentage of antibodies that bind to native proteins. As set forth, full-length sCD14 comprises the consecutive amino acid sequences as recited.

Claims 29 and 30 currently contain allowable subject matter.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

James L. Grun, Ph.D.
November 12, 2004

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
11/13/04